202.942.5000 202.942.5999 Fax

555 Twelfth Street, NW Washington, DC 20004-1206

February 19, 2004

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Re:

U.S. Application No. 10/643,681

Filed:

August 18, 2003

Title:

Methods for Regulating Gastrointestinal Motility

Applicants:

Orville G. KOLTERMAN et al.

Atty. Docket: 18528.642 / 254/057CON

Sir:

The following documents are forwarded herewith for appropriate action by the U.S. Patent and Trademark Office (PTO):

- 1. an Information Disclosure Statement;
- 2. a PTO-1449 Form (11 pages); and
- 3. a return postcard.

Please stamp the attached postcard with the filing date of these documents and return it to our courier.

In the event that extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned. Applicants do not believe any fees are due in conjunction with this filing. However, if any fees under 37 C.F.R. §§ 1.16 or 1.17 are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Arnold & Porter Deposit Account No. 50-2387, referencing matter number 18528.642. A duplicate copy of this letter is enclosed.

Respectfully submitted,

Il Moso

David R. Marsh (Reg. No. 41,408)

Milan M. Vinnola (Reg. No. 45,979)

Attachments



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Orville G. KOLTERMAN et al.

Application No. 10/643,681

Filed: August 18, 2003

For: Methods for Regulating Gastrointestinal Motility

Group Art Unit: 1646

Examiner: To Be Assigned

Atty. Docket: 18528.642 / 254/057CON

Confirmation No.: 4614

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

The attention of the Examiner is invited to the references listed on the attached Form PTO-1449. These references were previously considered in earlier filed U.S. Patent Application Serial No. 09/572,062, filed May 22, 2000, which issued as U.S. Patent No. 6,608,029, which is a continuation of U.S. Patent Application Serial No. 08/302,069, filed September 7, 1994, which issued as U.S. Patent No. 6,114,304, which is a continuation-in-part of U.S. Application Serial No. 08/118,381, filed September 7, 1993, now abandoned, upon which the instant application relies on for an earlier effective filing date under 35 U.S.C. 120. Applicants further submit that the references filed in the Information Disclosure Statement in the earlier applications complied with 37 C.F.R. 1.98(a)-(c). Accordingly, Applicants submit that under 37 C.F.R. 1.98(d)(1)-(2), copies of the listed references need not be provided. However, the Examiner is requested to notify the Applicants should he/she require a copy of any or all of the listed references.

It is respectfully requested that the information above be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Because this Information Disclosure Statement is being submitted prior to issuance of the first action on the merits of the above-captioned application, no certification or fee is required.

Respectfully submitted,

David R. Marsh (Reg. No. 41,408) Milan M. Vinnola (Reg. No. 45,979)

Date: February 19, 2004

ARNOLD & PORTER 555 Twelfth Street, N.W. Washington, D.C. 20004-1206 (202) 942-5000 telephone (202) 942-5999 facsimile

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INFORMATION DISCLOSSIVE STATEMENT
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ATTY. DOCKET NO.	APPLICATION NO.
18528.642	10/643,681
APPLICANTS	
Orville G. KOLTERMAN et al.	
FILING DATE	GROUP
August 18, 2003	1646

U.S. PATENT DOCUMENTS EXAMINER DOCUMENT SUB-NUMBER DATE NAME **CLASS CLASS** FILING DATE **INITIAL** 5,124,314 6/1992 AA1 Cooper 11/1992 AB1 5,166,192 Mathias AC1 5,175,145 12/1992 Cooper 2/1993 5,187,154 Phillips et al. AD1 5,234,906 8/1993 Young et al. AE1 5,260,275 11/1993 Cooper et al. AF1 AG1 5,264,372 11/1993 Beaumont et al. 5,266,561 11/1993 AH1 Cooper et al. 5,281,581 1/1994 AI1 Cooper et al. 5,367,052 11/1994 AJ1 Cooper et al. AK1 5,376,638 12/1994 Young et al. AL1 5,580,953 12/1996 Albrecht et al. 11/1997 Gaeta et al. AM1 5,686,411 AN1 6,114,304 9/2000 Kolterman et al. FOREIGN PATENT DOCUMENTS **EXAMINER** DOCUMENT SUB-INITIAL NUMBER DATE COUNTRY **CLASS CLASS** TRANSLATION Yes AN1 0 289 287 A2 11/1988 Europe No Yes 93/10146 5/1993 **PCT** AO1 No Yes AP1 93/10147 5/1993 **PCT** No Yes 92/20367 11/1992 **PCT** AQ1 No OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR1

Alam et al., "Selective Antagonism of Calcitonin-induced Osteoclastic Quiescence (Q Effect) by Human Calcitonin Gene-Related Peptide-(Val⁸Phe³⁷)", <u>Biochem. Biophys. Res. Commun.</u>, 179(1):134-139 (1991)

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· · · · · ·		OTHER (Including Author, Title, Date, Pertinent Pages, etc.)
	AA2	Amara et al., "Expression in Brain of a Messenger RNA Encoding a Novel Neuropeptide Homologous to Calcitonin Gene-Related Peptide", Science, 229:1094-1097 (1985)
	AB2	Brain et al., "Amylin Amide, Which is Structurally Similar to Calcitonin Gene-Related Peptide (CGRP), Stimulates Increased Blood Flow In Vivo", <u>Eur. J. Pharmacol.</u> , 183:221 (1990)
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	AF2	Camilleri & Malagelada, "Abnormal Intestinal Motility in Diabetes with the Gastroparesis Syndrome", <u>European Journal of Clinical Investigation</u> , 14:420-427 (1984)
	AG2	Campbell et al., "Gastric Emptying in Diabetic Autonomic Neuropathy", Gut, 18:462-467 (1977)
	АН2	Cavallo-Perin et al., "Gastric Emptying of Liquids and Solids Evaluated by Acetaminophen Test in Diabetic Patients with and without Autonomic Neuropathy", European Review for Medical & Pharmacological Sciences, XIII:205-209 (1991)
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	АА3	Cooper et al., "Purification and Characterization of a Peptide from Amyloid-Rich Pancreases of Type 2 Diabetic Patients", Proc. Natl. Acad. Sci. USA, 84:8628-8632 (1987)		
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	AE3	Cooper et al., "Amylin Action: Physiologic Basis and Pathologic Correlations", Diabetes, 497-500 (1991)		
	AF3	Cotroneo et al., "Gastric Emptying Rate and Hormonal Response in Type II Diabetics", <u>Diabetes Res.</u> , 17:99-104 (1991)		
	AG3	Daniel et al., "Use of Glucagon in the Treatment of Acute Diverticulitis", Br. Med. J., 3:720 (1974)		
	АН3	Dao et al., "Lack of Modulation of Gastric Emptying by Acute Hyperglycemia in Type 2 Diabetes Mellitus", Gastroenterology, 98:A342 (1990)		
	AI3	Deems et al., "Amylin or CGRP (-37) Fragments Reverse Amylin-Induced Inhibition of ¹⁴ C-Glycogen Accumulation", <u>Biochem. Biophys. Res. Comm.</u> , 181(1):116-120 (1991)		
	AJ3	Eisenberg et al., "Synchronous Gastric Motor and Secretory Activity in Normal and Diabetic Dogs: The importance of Variation in Blood Sugar Levels", <u>Bulletin de la Societe Internationale de Chirurgie</u> , 3:191-198 (1972)		
·	AK3	Feldman et al., "Abnormal Gastric Function in Longstanding, Insulin-Dependent Diabetic Patients", Gastroenterology, 77:12-17 (1979)		
	AL3	Feldman et al., "Disorders of Gastrointestinal Motility Associated with Diabetes Mellitus", Ann. Int. Med., 98:378-384 (1983)		
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	AA4	Patients", Gastroenterology, 87:895-9	Solid Radiopaque Markers: Studies in 002 (1984)	Healthy Subjects and Diabetic
	AB4	Follett et al., "Effect of Amylin on In 39(1):39A (1991)	sulin Receptor Kinase Activity In Vivo	in the Rat", Clinical Research,
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	AD4	Franken <i>et al.</i> , "The Use of Glucagon in Hydrostatic Reduction of Intussusception: A Double-Blind Study of 30 Patients", Radiology, 146:687 (1983)		
	AE4	Fraser et al., "Hyperglycaemia slows gastric emptying in Type 1 (insulin-dependent) diabetes mellitus", Diabetologia, 33:675-680 (1990)		
	AF4	Fraser et al., "Hyperglycaemia Stimulates Pyloric Motility in Normal Subjects", Gut, 32:475-478 (1991)		
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	АН4	Frontoni <i>et al.</i> , "In Vivo Insulin Resistance Induced by Amylin Primarily Through Inhibition of Insulin-Stimulated Glycogen Synthesis in Skeletal Muscle", <u>Diabetes</u> , 40:568-573 (1991)		
	Gaber et al., "Changes in Gastric Emptying in Recipients of Successful Combined Pancreas-Kidney Transplants" <u>Dig. Dis.</u> , 9:437-443 (1991)			bined Pancreas-Kidney Transplants",
	Galeazza et al., "Islet Amyloid Polypeptide (IAPP) Competes for Two Binding Sites of CGRP", Peptides, 12:585 591 (1991)			ng Sites of CGRP", Peptides, 12:585-
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			Orville G. KOLTERMAN et al.	
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	AB5	Gill et al., "Effects of Ciglitazone on Obese-Diabetic Viable Yellow Mice"	Endogenous Plasma Islet Amyloid Poly ', <u>Life Sciences</u> , 48:703-710 (1991)	peptide and Insulin Sensitivity in
	AC5	Glauser et al., "Intravenous Glucagon in the Management of Esophageal Food Obstruction", J. Am. Coll. Emergency Physns., 8:228 (1979)		
	AD5	Gomez-Foix et al., "Anti-Insulin Effects of Amylin and Calcitonin-Gene-Related Peptide on Hepatic Glycogenmetabolism", Biochem. J., 276:607-610 (1991)		
	AE5	Goodman and Gilman's The Pharmacological Basis of Therapeutics, Chapter 38, Pergamon Press, Eighth Edition (1990)		
	AF5	Hartter et al., "Basal and Stimulated Plasma Levels of Pancreatic Amylin Indicate its Co-Secretion with Insulin in Humans", <u>Diabetologia</u> , 34:52-54 (1991)		
	AG5	Horowitz et al., "Gastric and Oesophageal Emptying in Patients with Type 2 (Non-Insulin-Dependent) Diabetes Mellitus", <u>Diabetologia</u> , 32:151-159 (1989)		
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	AI5	Horowitz et al., "Relationships Between Oesophageal Transit and Solid and Liquid Gastric Emptying in Diabetes Mellitus", Eur. J. Nucl. Med., 18:229-234 (1991)		
	AJ5	Horowitz et al., "Relationship Between Oral Glucose Tolerance and Gastric Emptying in Normal Healthy Subjects", <u>Diabetologia</u> , 36:857-862 (1993)		
	AK5	Horowitz et al., "Disordered Gastric Motor Function in Diabetes Mellitus", <u>Diabetologia</u> , 37:543-551 (1994)		
	AL5	Huang et al., "Hyperamylinemia, Hyperinsulinemia, and Insulin Resistance in Genetically Obese LA/N-cp Rats", Hypertension, 19:I-101-I-109 (1992)		
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AB6	Isal et al., "Gastric Emptying of Sol	id Radiopague Markers in Diab	etic Patients", <u>Gastroenterology</u> , 88:1094 (1985)
AC6	Janssens <i>et al.</i> , "Improvement of Ga 322:1028-1031 (1990)	stric Emptying in Diabetic Gas	troparesis by Erythromycin", N. Engl. J. Med.,
AD6	Jonderko et al., "Calcitonin Suppresses Gastric Emptying of a Radiolabelled Solid Meal in Humans", <u>Br. J. Clin. Pharmacol.</u> , 24:103-105 (1987)		
AE6	Jonderko et al., "Effect of Calcitonin on Gastric Emptying", Digestion, 40:191-196 (1988)		
AF6	Jonderko, "Effect of Calcitonin on Gastric Emptying in Patients with an Active Duodenal Ulcer", <u>Gut</u> , 30:430-435 (1989)		
AG6	Kanatsuka et al., "Secretion of Islet Amyloid Polypeptide in Response to Glucose", FEBS Lett., 259(1):199-201 (1989)		
АН6	Katsoulis et al., "Effects of Calcitonin Gene Related Peptides (CGRP), Calcitonin (CT) and Islet Amyloid Polypeptide (IAPP) on Gastric Motility of Guinea Pig and Rat", Regul. Pept., 26:77 (1989)		
Al6	Keshavarzian et al., "Gastric Emptying in Patients with Insulin-Requiring Diabetes Mellitus", Am. J. Gastroent., 82:29-35 (1987)		
AJ6	AJ6 Koda et al., "Amylin Concentrations and Glucose Control", The Lancet, 339:1179-1180 (1992)		
AK6	Kolterman et al., "Infusion of Amylin Agonist, Reduces Postprandial Hyperglycemia in Subjects with Type I Diabetes (IDDM)", Clinical Research, 42(1):87A (1994)		
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	AA7	Koopmans et al., "Amylin Induced In Amylin than Peripheral Tissues", Dia	a Vivo Insulin Resistance in Conscious Fabetologia, 34:218-224 (1991)	Rats: The Liver is More Sensitive to
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	AC7 Lenz, "Calcitonin and CGRP Inhibit Gastrointestinal Transit Via Distinct Neuronal Pathways", Am. J. Physiol. Soc'y, G920-G924 (1988)			uronal Pathways", Am. J. Physiol.
	AD7	Lin et al., "Gastric Emptying of Solid Meal in Diabetic Patients", Nippon Shokakigyo Gakkai Zasshi, 84:1-5 (1987)		
	AE7	Loo et al., "Gastric Emptying in Patients with Diabetes Mellitus", Gastroenterology, 86:485-494 (1984)		
	AF7	Lupien and Young, "No Measurable Effect of Amylin on Lipolysis in Either White or Brown Isolated Adipocytes from Rates", <u>Diabetes Nutrition and Metabolism - Clinical and Experimental</u> , 6:13-18 (1993)		
	AG7	MacGregor et al., "The Effect of Acute Hyperglycemia on Gastric Emptying in Man", Gastroenterology, 70:190-196 (1976)		
	АН7	McCallum et al., "Definition of a Gastric Emptying Abnormality in Patients with Anorexia Nervosa", <u>Digestive</u> <u>Diseases and Sciences</u> , 30(8):713-722 (1985)		
	AI7	Mecklenbeck et al., "Gastric Emptying in Diabetic Neuropathy: Two Different Forms of Disturbed Kinetics", Euro. J. Nucl. Med., 18:FP-3H3-1 (1991)		
	AJ7	Moberg & Carlberger, "Gastric Emptying in Healthy Subjects and in Patients with Various Malabsorptive States", Scand. J. Gastroent., 9:17-21(1973)		
	AK7	Molina et al., "Induction of Insulin Resistance In Vivo by Amylin and Calcitonin Gene-Related Peptide", <u>Diabetes</u> , 39:260-265 (1990)		
	AL7	Moore and Rink, "Amylin Activates Adenylyl Cyclase in Rat Soleus Muscle", <u>Diabetes</u> , 42:5, 821 (1993)		
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AB8	Nagai et al., "A Case of Diabetic Neuropathy Accompanied by Relapsing Paralytic Ileus Due to Omeprazole Administration", J. Japan. Diab. Soc., 36(9):733-739 (1993)		
AC8	Nakanome et al., Tohoku J. Exp. Me	d., 139:205-215 (1983)	
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AE8	Ogawa et al., "Amylin Secretion from the Rat Pancreas and its Selective Loss after Streptozotocin Treatment", <u>J. Clin. Invest.</u> , 85:973-976 (1990)		
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AG8	Pehling et al., "Abnormal Meal Carbohydrate Disposition in Insulin-Dependent Diabetes", J. Clin. Invest., 74:985-991 (1984)		
АН8	Phillips et al., "Rapid Gastric Emptying in Patients with Early Non-Insulin-Dependent Diabetes Mellitus", N. Eng. J. Med., 10:130-131 (1991)		
AI8	Phillips et al., "Rapid Gastric Emptying of an Oral Glucose Solution in Type 2 Diabetes Mellitus", J. Nucl. Med., 33:1496-1500 (1992)		
АЈ8	Phillips et al., "Reduced Postprandial Blood Glucose Levels in Recently Diagnosed Non-Insulin-Dependent Diabetics Secondary to Pharmacologically Induced Delayed Gastric Emptying", <u>Digestive Diseases and Sciences</u> , 38:51-58 (1993)		
AK8	Plourde <i>et al.</i> , "CGRP 8027 Blocks the Inhibition of Gastric Emptying Induced by Intravenous Injection of α-CGRP in Rats", <u>Life Sciences</u> , 52:857-862 (1993)		ced by Intravenous Injection of α-
AL8	Raybould <i>et al.</i> , "Central Nervous System Action of Calcitonin Gene-Related Peptide to Inhibit Gastric Emptying in the Conscious Rat", Peptides, 9:735-739 (1988)		
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			etc.)
AA9	"Remington's Pharmaceutical Science TABLE OF CONTENTS	ces", Alfonso Gennaro, Editor,	Mack Publishing Company, 18 th Edition,
AB9	Roden et al., "Effects of Islet Amylo Isolated Perfused Rat Liver", <u>Diabete</u>		lin Resistance and Glucose Production in the
AC9	Saltzman and McCallum, "Diabetes	and the Stomach", Yale J. Biol.	<u>Med.</u> , 56:179-187 (1983)
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			ATTY. DOCKET NO.	APPLICATION NO.			
			18528.642	10/643,681			
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